

Amendments to the Specification:

At page 1, the heading “Cross-Reference to Related Case” was replaced with the following heading:

Cross-Reference to Related Case Applications

Paragraph [0001] was replaced with the following paragraph:

This application is a continuation application of U.S. patent application Serial No. 09/992,359, filed on November 14, 2001, which claims benefit of and priority to U.S. provisional patent application Serial No. 60/248,808, filed on November 15, 2000, the entire disclosures of which [[is]] are incorporated by reference herein~~by reference in its entirety.~~

Paragraph [0016] was replaced with the following paragraph:

In another aspect, the invention features a surgical device that includes a sling, a first tether with a proximal end coupled to a distal end of the sling, a second tether with a distal end coupled to a proximal end of the sling, a curved needle coupled to a distal end of the first tether, and a dilator disposed along the first tether between the curved needle and the distal end of the sling.

Paragraph [0026] was replaced with the following paragraph:

Fig. 3 shows a transverse cross-sectional view of the surgical device of Fig. 2 along section ~~2A-2A~~ 3-3.

Paragraph [0030] was replaced with the following paragraph:

Figs. 7A-C show three exemplary embodiments of transverse cross-sectional views of the surgical device of Fig. 6 along section ~~6A-6A~~ 7A, 7B, 7C - 7A, 7B, 7C.

Paragraph [0037] was replaced with the following paragraph:

The curvature of the needle 20 should be sufficient to pass around a urethra 104 from a vaginal cavity 102, as shown in Fig. 9. The needle 20 may be of any size and/or type. For example, the needle 20 may be a 1/2 circle or a 3/8 circle needle. The needle 20 may be of any point configuration such as a cutting point or a reverse cutting point. The size of the needle 20

may also range from 12 mm- 25 mm. Examples of needles 20 include, but are not limited to, Ethicon PC-12 and PS-5. (Ethicon, Inc., Somerville, N.J.)

Paragraph [0038] was replaced with the following paragraph:

The first tether 30 and the second tether 60 can be formed from a suture, a wire, a portion of the sling 50, or any other material that is strong enough to resist breaking as the surgical device 10 is passed through the body. The tethers 30, 60 may be attached to the sling 50 in any number of ways known in the art such as tying, suturing, bonding, or molding. The tethers 30, 60 can also be used to secure the sling 50 in place once it is disposed around the urethra 104. The sling 50 is secured by the tethers 30, 60 to the interior portion [[7]] of the vaginal wall [[6]]. Typically, the tethers 30, 60 remaining in the vaginal wall [[6]] will eventually be covered with endothelial tissue. In some embodiments, the tether 30, 60 is a suture. The suture can be a non-absorbable suture such as a polyester, for example Dacron® polyester (DuPont, Wilmington, Delaware), an expanded polytetrafluoroethylene (EPTFE), such as Gore-Tex® (W.L. Gore & Associates, Inc., Newark, Delaware), a polypropylene, or a braided silk. Other suitable materials that can be used as a suture will be apparent to those skilled in the art.

Paragraph [0039] was replaced with the following paragraph:

The dilator 40 can be made of a semi-rigid plastic material. Examples of such materials include, but are not limited to, polyethylene terephthalate (PET), polyethylene (PE), or ethylene vinyl acetate (EVA). The dilator 40 is sufficiently rigid to push through the tissue of the body and create an opening for the sling 50, but also sufficiently flexible to curve axially around the urethra 104, following the path of the curved needle 20, as shown in Figs. 9 and 10.

Paragraph [0040] was replaced with the following paragraph:

The distal end 42 of the dilator [[42]]40 can be substantially similar in size to the proximal end 24 of the curved needle [[24]]20. From the distal end 42 of the dilator [[42]]40, the dilator 40 can expand in a planar direction, a cylindrical direction (i.e., increasing circumference), or combination of both a planar direction and a cylindrical direction. For example, if the dilator 40 expands in a planar direction, the resultant dilator 40 is substantially flat and triangular in shape. The dilator 40 preferably expands until it reaches a size not less than the width of the sling 50, to ensure that the opening created by the dilator 40 will accommodate

the width of the sling 50. The dilator 40 can terminate at a maximum width, whereby the passage of the dilator 40 through the body creates an opening sufficiently wide to allow the sling 50 to pass through the body. The length of the dilator 40 can be sufficient to allow the dilator 40 to be grasped with forceps and pulled and/or pushed through the body, if necessary.

Paragraph [0055] was replaced with the following paragraph:

The pouch 470 can be clear or translucent to permit visualization of the sling 450 within. The pouch 470 can also be made of a porous material such as polyethylene, polyethylene terephthalate, or vinyl made porous by methods well known in the art. Other suitable materials will be apparent to those skilled in the art. The pouch 470 can be adapted to receive a dilator 440 and a sling 450. The surgical device 410 may also include a stiffener 446 as shown in any one of Figs. 7A-C. Figs. 7A-C depict three variations of transverse cross-sections of the surgical device 410 along section ~~6A-6A~~ 7A, 7B, 7C - 7A, 7B, 7C of Fig. 6. The stiffener 446 and sling 450 may be housed in the pouch 470 (Fig. 7A). The sling 450 may be housed in the stiffener 446 that is housed in the pouch 470 (Fig. 7B). The sling 450 may be housed in the pouch 470; however, the stiffener 446 is adjacent but not housed in the pouch 470 (Fig. 7C). The length of the pouch 470 may be varied depending upon the length of the sling 450. Alternatively, the pouch 470 may be greater or lesser in length than the sling 450. The pouch 470 is adapted to releasably engage the sling 450.

Paragraph [0060] was replaced with the following paragraph:

As the dilator 440 is withdrawn from the body into the vaginal cavity 102, the appropriate marking(s) 448 can be used to alert the user to secure the second tether 460 to the anterior portion of the vaginal wall 108 to prevent further passage of the sling 450 and maintain its position above the anterior portion [[109]] of the urethra 104. The dilator 440 is then withdrawn from the body along with the pouch 470. The sling 450 is thereby disposed axially to the urethra 104. The first tether 430 is used to secure the sling 450 with enough tension to pull the urethra 104 against the vaginal wall 108 to thereby provide proper coaptation to the urethra 104.

Paragraph [0063] was replaced with the following paragraph:

In another method according to the invention, an opening or pocket around the urethra 104 is created to receive the sling 450. This opening or pocket can be created prior to passing

the surgical device 410 through the body. The opening or pocket may be created in a variety of ways. For example, the opening may be created by hydrodissection in which a bolus of saline or other sterile solution can be injected through the anterior portion of the vaginal wall 108 targeting the tissue that surrounds the urethra 104. For this procedure, the opening or pocket to be created is made to the anterior portion [[109]] of the urethra 104. An advantage of hydrodissection is that the urethra 104 is separated from the surrounding tissue along tissue planes to create an opening or pocket to receive the sling 450.

Paragraph [0065] was replaced with the following paragraph:

In an alternative approach, the opening or pocket can be created by balloon dissection in which a non-inflated, expandable balloon is introduced into the tissue between the anterior portion [[109]] of the urethra 104 and the surrounding tissue. When the balloon is expanded, the surrounding tissue is dilated or torn, generating an opening or pocket of sufficient size to receive the sling 450.

Paragraph [0066] was replaced with the following paragraph:

In yet another approach, the opening or pocket can be created by dissecting the tissue between the anterior portion [[109]] of the urethra 104 and the surrounding tissue with [[of]] blunt dissectors and/or sharp cutters to accommodate the sling 450.